

others lawfully engaged in dispensing prescription drugs; 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement; and 503(b)(4)—a number of the articles of drug were subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 2-7-62. Default—destruction.

7011. Proloid tablets. (F.D.C. No. 46740. S. No. 209 T.)

QUANTITY: 5 500-tablet bags at Miami, Fla., in possession of Flamingo Wholesale, Inc.

SHIPPED: Prior to 8-10-61, from Morris Plains, N.J.

LABEL IN PART: (Bag) "Proloid $\frac{1}{2}$ gr. * * * Cost 72041/500 net."

LIBELED: 11-28-61, S. Dist. Fla.

CHARGE: 502(b)(1)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(1)—the label of the article failed to bear the common or usual name of the drug; 502(f)(1)—the label of the article failed to bear adequate directions for use and the article was not exempt from such requirement since it was a drug subject to 503(b)(1) and its label failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug; and 503(b)(4)—the article was subject to the provisions of 503(b)(1) and the label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 1-30-62. Default—destruction.

7012. Hematonic Formula capsules and B complex capsules. (F.D.C. No. 46747. S. Nos. 7-192/3 T.)

QUANTITY: 56 ctnd. btls. of *Hematonic Formula capsules* and 15 ctnd. btls. of *B complex capsules*, at Gloucester, Mass.

SHIPPED: Between 11-17-59 and 6-21-60, from Dallas, Tex.

LABEL IN PART: (Ctn. and btl.) "100 Capsules Hematonic Formula An Anti-Anemia Formula Vitamin B₁₂-B₁, Liver Stomach with Intrinsic Factors and Iron * * * Each capsule contains: * * * Folic Acid 1 Mg." and (ctn. and btl.) "100 Capsules High Potency B Complex With Vitamin B-12, Minerals, Liver, Lipotropes and Intrinsic Factors * * * Each Coated Tablet Contains: * * * Folic Acid 0.5 Mg."

LIBELED: 12-1-61, Dist. Mass.

CHARGE: 503(b)(4)—while held for sale, the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-15-62. Default—destruction.

7013. Materfol Elixir. (F.D.C. No. 46461. S. Nos. 39-541/2 T.)

QUANTITY: 23 4-oz. btls. and 27 cases, each containing 12 8-oz. btls., at Santurce, P.R.

SHIPPED: 5-4-60 (27-case lot) and 5-14-61 (23-btl. lot), from Hialeah, Fla., by Delta Pharmaceuticals, Inc.

LABEL IN PART: (Btl.) "8 Fl. Oz. [or "4 Fl. Oz."] List 517 Materfol Elixir (Hematinic) * * * Each Teaspoonful (5 CC) Contains: Folic Acid 1 Mg. Liver Extract Equivalent to 2 Grams of Fresh Liver Vitamin B₁₂ (From Cobalamin Concentrate) 5 MCG Iron Peptonate 250 MG (44.4 Mg. Iron) Alcohol (By Volume) 10% In a Palatable Vehicle Containing Sorbitol * * * Delta Pharmaceuticals, Inc. Miami - Florida * * * Therapeutic Dose in Anemia: Adults 1 or 2 teaspoonfuls (5 cc) 3 or 4 times a day * * * Children - One half teaspoonful 3 or 4 times a day."

LIBELED: 10-25-61, Dist. P.R.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations and suggestions that the article was adequate and effective for the treatment of all anemias; 503(b) (4)—the article was a drug to which 503(b) (1) applied, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 1-5-62. Default—destruction.

7014. Viritabs tablets. (F.D.C. No. 46466. S. Nos. 39-550 T, 39-565/66 T.)

QUANTITY: 37 100-tablet btls., 478 50-tablet btls., and 728 6-tablet boxes, at Santurce, P.R.

SHIPPED: Between 9-14-59 and 7-6-61, from Newark, N.J., by Benson Pharmacal Corp.

LABEL IN PART: (100-tablet btl.) "Benson * * * Viritabs * * * Benson Pharmacal Co., Inc., New York 4, N.Y. * * * Each Tablet contains: Testosterone 2 Mgm. * * * Yohimbine Hydrochloride 5 Mgm."; (50-tablet btl.) "Benson * * * Viritabs * * * Benson Pharmacal Co., Inc., New York 4, N.Y. * * * Indicado en casos de impotencia sexual preveniente * * * Cada tableta contiene: Testosterona 2 mgm. * * * Chlorhidrato de yohimbina 5 mgm."; and (box) "Muestras Gratis * * * Benson Viritabs * * * Benson Pharmacal Co., Inc., New York, N.Y. * * * Cada tablets contiene: Testosterona 2 mgm. * * * Clorhidrato de yohimbina 5 mgm."

ACCOMPANYING LABELING: Leaflet in English entitled "Viritabs" and leaflet in Spanish entitled "Viritabs."

RESULTS OF INVESTIGATION: The leaflets were shipped on 7-6-61, to the dealer, by Benson Pharmacal Corp., with the 50-tablet bottles and the 6-tablet boxes.

LIBELED: 10-24-61, Dist. P.R.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment of sexual impotence, lack of virility and vigor, weakening of sexual potency, hypogonadism, benign prostatic hypertrophy, and to stimulate energy and rejuvenate youth; and 503(b) (4)—the article was a drug subject to the provisions of 503(b) (1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without a prescription."

DISPOSITION: 1-9-62. Default—destruction.